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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,839	05/18/2006	Derek Nigel John Hart	DAVI257.002APC	8032

20995 7590 04/16/2009  
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IRVINE, CA 92614

EXAMINER
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GUSSOW, ANNE

ART UNIT	PAPER NUMBER
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1643

NOTIFICATION DATE	DELIVERY MODE
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04/16/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com  
eOAPilot@kmob.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/537,839	<b>Applicant(s)</b> HART ET AL.	
	<b>Examiner</b> ANNE M. GUSSOW	<b>Art Unit</b> 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 57-65 is/are pending in the application.
- 4a) Of the above claim(s) 62-65 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 57-61 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>Sequence alignment</u>                 |

### **DETAILED ACTION**

1. The finality of the previous Office action has been withdrawn upon further consideration by the examiner, in view of the NEW GROUNDS of Rejection below.
2. Claims 1-56 have been canceled.  
Claims 57-62 have been amended.  
Claims 62-65 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on February 6, 2008.
3. Claims 57-61 are under examination.

### ***Rejections Withdrawn***

4. The rejection of claims 57-61 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of applicant's amendment to the claims.
5. The rejection of claim 57 under 35 U.S.C. 112, first paragraph, as introducing new matter into the claims is withdrawn in view of applicant's amendment to the claims.

***NEW GROUNDS of Rejection***

***Claim Objections***

6. Claim 58 is objected to because of the following informalities: the claim contains a grammatical error, "is" should read "are". Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 57-61 are rejected under 35 U.S.C. 102(b) as being anticipated by Birse, et al. (WO/2001/090304, published November 29, 2001) as evidenced by the specification.

The claims recite isolated antibodies that specifically bind a protein comprising the amino acid sequence encoded by the polynucleotide sequence of SEQ ID NO: 4, wherein said antibodies are monoclonal antibodies, wherein said antibodies are polyclonal antibodies, wherein said antibodies are synthetic antibodies, wherein said antibodies are Fab fragments.

Birse, et al. teach a polypeptide sequence that is identical to the instant SEQ ID No. 5 (see sequence alignment). The specification discloses that SEQ ID No. 5 is the polypeptide encoded by SEQ ID No. 4. Birse, et al. teach antibodies that bind to the polypeptide and that antibodies may be polyclonal, monoclonal, and Fab fragments (pages 1779-1781). Regarding the synthetic antibody of claim 60, one of ordinary skill in the art would know that antibodies, such as Fab fragments or recombinant antibodies, would be synthetic antibodies. Since Birse, et al. teach antibodies that bind to a polypeptide sequence which is identical to the polypeptide encoded by SEQ ID No. 4, all the limitations of the claims have been met.

9. Claims 57-61 are rejected under 35 U.S.C. 102(b) as being anticipated by Tang, et al. (WO/2001/079449, published October 25, 2001), as evidenced by the specification.

The claims have been described supra.

Tang, et al. teach a polypeptide sequence that is 75.2% identical to the instant SEQ ID No. 5. The specification discloses that SEQ ID No. 5 is the polypeptide encoded by SEQ ID No. 4. Although the polypeptides are not identical, the polypeptide of Tang, et al. shares large regions of identity to the instant SEQ ID No. 5 and because of these regions of homology antibodies that bind to the polypeptide of Tang, et al. would also bind to the polypeptide of SEQ ID No. 5. Tang, et al. teach antibodies that bind to antigen may be polyclonal, monoclonal, or Fab fragments (page 74). Regarding the synthetic antibody of claim 60, one of ordinary skill in the art would know that

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antibodies, such as Fab fragments or recombinant antibodies, would be synthetic antibodies. Since Tang, et al. teach antibodies that would bind to the polypeptide encoded by the instant SEQ ID No. 4, all the limitations of the claims have been met.

10. Claims 57-61 are rejected under 35 U.S.C. 102(e) as being anticipated by Shi, et al. (US PAT 7,381,800, priority to at least January 25, 2001), as evidenced by the specification.

The claims have been described supra.

Shi, et al. teach antibodies that bind to a polypeptide which is 99.6% identical to the instant SEQ ID No. 5. The specification discloses that SEQ ID No. 5 is the polypeptide encoded by SEQ ID No. 4. Although the polypeptides are not identical, the polypeptide of Shi, et al. has only a single amino acid residue difference from the instant SEQ ID No. 5 and because of the large regions of identity between the two sequences antibodies that bind to the polypeptide of Shi, et al. would also bind to the polypeptide of SEQ ID No. 5. Shi, et al. teach antibodies that bind to antigen may be polyclonal, monoclonal, or Fab fragments (columns 69 and 70). Regarding the synthetic antibody of claim 60, one of ordinary skill in the art would know that antibodies, such as Fab fragments or recombinant antibodies, would be synthetic antibodies. Since Shi, et al. teach antibodies that would bind to the polypeptide encoded by the instant SEQ ID No. 4, all the limitations of the claims have been met.

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11. Claims 57-61 rejected under 35 U.S.C. 102(e) as being anticipated by Rosen, et al. (US PAT 7,368,531, filed March 19, 2002), as evidenced by the specification.

The claims have been described supra.

Rosen, et al. teach antibodies that bind to a polypeptide which is 74.2% identical to the instant SEQ ID No. 5. The specification discloses that SEQ ID No. 5 is the polypeptide encoded by SEQ ID No. 4. Although the polypeptides are not identical, the polypeptide of Rosen, et al. shares large regions of identity to the instant SEQ ID No. 5 and because of these regions of homology antibodies that bind to the polypeptide of Rosen, et al. would also bind to the polypeptide of SEQ ID No. 5. Rosen, et al. teach antibodies that bind to antigen may be polyclonal, monoclonal, or Fab fragments (column 320). Regarding the synthetic antibody of claim 60, one of ordinary skill in the art would know that antibodies, such as Fab fragments or recombinant antibodies, would be synthetic antibodies. Since Rosen, et al. teach antibodies that would bind to the polypeptide encoded by the instant SEQ ID No. 4, all the limitations of the claims have been met.

### ***Conclusion***

12. No claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANNE M. GUSSOW whose telephone number is

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(571)272-6047. The examiner can normally be reached on Monday - Friday 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Anne M. Gussow  
April 9, 2009

/Anne M Gussow/  
Examiner, Art Unit 1643